Citation:

Pal S, Lim S, Egger G. The effect of a low glycaemic index breakfast on blood glucose, insulin, lipid profiles, blood pressure, body weight, body composition and satiety in obese and overweight individuals: A pilot study. *J Am Coll Nutr.* 2008 Jun; 27(3): 387-393.

PubMed ID: 18838526

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate whether altering the glycemic index of one meal for 21 days in obese individuals would have a favorable effect on satiety, fasting serum glucose, insulin, LDL- and HDL-cholesterol and triglycerides (TG).

Inclusion Criteria:

- Hypercholesterolemic (5.5mmol per L or higher plasma cholesterol)
- Obese or overweight
- Between 25 and 65 years of age.

Exclusion Criteria:

- Current chronic medical disease
- Pregnancy
- Hormone replacement therapy (HRT)
- Lipid-lowering medication
- Use of steroids and other agents that may influence lipid metabolism
- Use of warfarin
- Smoking
- Hyper- or hypothyroidism
- Diabetes mellitus
- Cardiovascular events within the last six months
- Psychological unsuitability
- Major systemic diseases
- Gastrointestinal problems
- Proteinuria
- Liver and renal failure

- Apolipoprotein genotype (E2/E2 exclusion).

Description of Study Protocol:

Recruitment

Volunteers were recruited from the community using poster advertising and the radio.

Design

Randomized cross-over trial with two three-week interventions separated by a three-week washout period.

Dietary Intake/Dietary Assessment Methodology

Dietary intake was monitored through the completion of three-day food diaries at the beginning (three days before baseline) and end of each intervention period (days 19 to 21).

Blinding Used

Single blinded study?

Intervention

- After baseline measurements, subjects were randomized to a three-week intervention period that consisted of breakfast meals of either low glycemic index or high glycemic index (breakfast items were provided). Subjects consumed a low- or high-glycemic index breakfast at 8:30 a.m. and usual lunch at 12:30 p.m. Subjects were instructed to maintain their habitual intakes for the other meals (ad libitum). Follow-up calls were made every three days to subjects to assist with compliance. The two intervention periods were separated by a washout period of 21 days
- Both breakfast meals provided the same energy, protein, fat and carbohydrate values within 6%.

Statistical Analysis

- Changes in all measurements during each dietary period (baseline vs. final data) were compared (low vs. high glycemic index)
- The two groups were compared using repeated measures analysis of variance taking into account the repeated measurements for each subject.

Data Collection Summary:

Timing of Measurements

- Three-day food diaries were completed during the the first three consecutive days before baseline and the last three consecutive days before final measurements (days 19-21)
- Satiety effects of the breakfast meals were assessed on the occasions when three-day food diaries were recorded
- Anthropomorphic measures, blood glucose and lipid profiles were measured before and after each intervention period.

Dependent Variables

- Weight
- Waist circumference
- Hip circumference
- Body fat percent
- Body mass index (BMI)
- Total cholesterol (TC)
- HDL-cholesterol (HDL-C)
- LDL-cholesterol (LDL-C)
- Triacylglyceride (TG)
- Fasting insulin
- Systolic and diastolic blood pressure (SBP and DBP)
- Insulin sensitivity (homeostasis model assessment score).

Independent Variables

- Low-glycemic index breakfast (glycemic load, 1,455; glycemic index,: 35)
- High-glycemic index breakfast (glycemic load, 2,960; glycemic index, 79).

Control Variables

- Age
- Weight
- Diet order
- Baseline lipid and glucose values
- Energy in each diet phase.

Description of Actual Data Sample:

- *Initial N:* 21 (five males, 16 females)
- *Attrition (final N):* 21
- *Age:* 25 to 65 years
- *Anthropometrics:* Mean (SEM) BMI for the two groups was 32.8 (0.95) and 30.5 (0.22)kg/m^2
- *Location:* Australia.

Summary of Results:

Key Findings

- Total daily energy intake was not different between the groups (P=0.45)
- Satiety ratings (adjusted for baseline values) were observed to be 7% higher after breakfast (P=0.014) and and 12% higher after lunch (P=0.034) when subjects consumed a low glycemic index breakfast compared to a high glycemic index breakfast
- Body weight, waist, body fat and hip measurements were not different between the groups. Fasting triacylglycerol; insulin; blood pressure; and total, HDL-C and LDL-C were also not affected
- Fasting glucose levels were lower when subjects were consuming a low glycemic index breakfast (4.88, SEM: 0.11mmol per L) for three weeks compared to when they were consuming a high glycemic index breakfast (5.11, SEM: 0.14mmol per L).

Author Conclusion:

This study found that modifying glycemic index in a single meal (i.e., breakfast) alone resulted in lower fasting blood glucose levels and induced satiety until lunch in obese, non-diabetic subjects, but did not decrease voluntary energy intake and therefore no weight loss occurred.

Reviewer Comments:

- *Author-identified limitations: A larger sample size and longer time period is needed to investigate the long-term benefits of breakfast meal modification*
- *Described as a "single-blinded study," but did not identify who was blinded.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes

2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	N/A
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	N/A
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A

5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	???
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	No
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	No
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	No
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes

8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	No
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes